NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES *ex rel.* PETRATOS, Plaintiff, v. GENENTECH, INC. and ROCHE GROUP Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 11-cv-3691 (DMC)(JAD)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon the Motion of Genentech, Inc. ("Genentech" or "Defendant") to dismiss the Complaint of Relator Gerasimos Petratos ("Relator"). Pursuant to FED. R. CIV. P 78, no oral argument was heard. Based on the following and for the reasons expressed herein, Defendant's Motion to Dismiss is **granted in part and denied in part**.

I. BACKGROUND[1]

Relator specializes in biomedical informatics. He began working at Roche Group ("Roche") in 2003. In summer 2009, Roche merged with Genentech. Genentech produces a biological cancer medicine called Avastin, which has been approved by the FDA for a number of indications. After the merger, Relator joined the Oncology Epidemiology Team (the "Team") and was involved in data analytics research and meetings with members of the the Avastin Drug Safety Team.

[1] The facts from this section are taken from the parties' pleadings.

Relator claims that after joining the Team, he learned that Genentech was intentionally and regularly underreporting the prevalence and severity of adverse effects caused by Avastin. Relator states that Genentech was basing its disclosures on databases that it knew lacked the information that would allow identification of at-risk subgroups that were more likely to suffer adverse events, and that Genentech had the ability to use more robust databases but failed to do so. Relator also claims that Genentech was not adequately examining and reporting dose-related effects of Avastin, thus obscuring situations where doses of Avastin should be lowered or eliminated to avoid serious side effects in particular subgroups. Relator claims that he made numerous suggestions to Genentech's management team in an attempt to correct these deficiencies, but that all of his suggestions were rejected.

In June 2010, an independent study found that Avastin "significantly increases the risk for high-grade proteinuria and nephritic syndrome" and that proteinuria was dose-dependent. Following publication of the article, Dr. Richard Lafayette of Stanford University contacted Genentech to see if the company could provide him information about Avastin patients with risk factors for renal failure. Relator claims that in November 2010, using the databases that Genentech chose to ignore, he generated an assessment to provide to Dr. Lafayette that demonstrated that Genentech was masking the dose-dependency of Avastin. The assessment also contained information concerning individuals who were at a significantly increased risk of experiencing severe adverse events due to Avastin's side effects. Relator states that he presented this data to Dr. Wei Dong, Global Head of the Oncology Epidemiology Team, and that Dr. Dong told him that his assessment would not be incorporated into Genentech's disclosures to regulator or to the public. Relator also claims that Dr. Dong directed him to cease further work in the area due to the "business risk" to Genentech's revenues. Relator alleges that Genentech then

continued to make false public disclosures that undermined the existence of risk factors surrounding Avastin.

Relator filed a Complaint on June 27, 2011 (ECF No. 1). The next day, the FDA held a hearing regarding a proposal to withdraw Avastin's metastatic breast cancer indication. On November 28, 2011, the FDA decided to withdraw approval for the metastatic breast cancer indication. In December 2012, Relator served the Complaint on Genentech and Roche. Genentech filed the instant Motion to Dismiss on July 17, 2013 (ECF No. 22). Relator filed an Opposition on October 1, 2013 (ECF No. 32). The United States filed a Statement of Interest on October 7, 2013 (ECF No. 35). Genentech filed a Reply on November 13, 2013 (ECF No. 37).

II. STANDARD OF REVIEW

In deciding a motion under FED. R. CIV. P. 12(b)(6), the District Court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." Phillips v. Cnty. of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). However, the plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions and a formulaic recitation of the elements of a cause of action will not do." Id. On a motion to dismiss, courts are "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986). Plaintiff's complaint is subject to the heightened pleading standard set forth in Ashcroft v. Iqbal:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. . . . Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the

well pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not "show[n]" - "that the pleader is entitled to relief."

556 U.S. 662, 678-679 (2009) (quoting Twombly, 550 U.S. at 557, 750).

II. DISCUSSION

A. Federal Claims

The False Claims Act ("FCA") imposes liability upon any individual who submits a "false or fraudulent claim for payment" to an officer or employee of the United States Government. 31 U.S.C. § 3729(a). A unique characteristic of the FCA is that it may be enforced by a private individual acting on the Government's behalf, known as a relator. 31 U.S.C. § 3730(b). Once the relator has filed a suit under the FCA, the Government may decide to intervene in the action and control the suit. 31 U.S.C. § 3730(c). Any eventual recovery belongs to the Government regardless of whether it intervenes. Id.

1) Counts One and Two

Count one alleges a violation of § 3729(a)(1)(A) of the FCA, which imposes liability on an individual who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Count two alleges a violation of § 3729(a)(1)(B), which imposes liability on an individual who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

Defendant argues that counts one and two[2] must be dismissed because Relator has not alleged the existence of a false claim.[3] In response, Relator argues that because Medicare only covers "reasonable and necessary" medical services, when a healthcare provider prescribes a

[2] Defendant actually makes these arguments with respect to counts one through four. However, as discussed below, they are only applicable to counts one and two.

[3] Although Relator argues that Defendant's motion incorrectly relies on an older version of the FCA, both versions require the existence of a false claim.

drug for a use that it not "reasonable and necessary," the provider's claim for reimbursement is "false" under the FCA. Thus, according to Relator, due to the undisclosed dangers of Avastin, "each time Genentech billed a physician or hospital . . . for Avastin, and the physician or hospital subsequently sought . . . reimbursement from the U.S. government, Genentech's submission of the bill to the doctor or hospital was itself a false claim on the United States" (Pl.'s Opp'n at 24). There are several problems with this argument. First, Relator's 104 page Complaint does not allege that *all* claims for reimbursement for Avastin were false claims. This appears to be a new theory raised for the first time in Relator's Opposition.

Second, in U.S. ex rel. Simpson v. Bayer Corp., No. 05-3895, 2013 WL 4710587, at *11 (D.N.J. Aug. 30, 2013), a case involving an off-label prescription, this District agreed with the defendant's contention that "[c]ourts and government reimbursement programs generally consider off-label uses to be medically accepted and thus 'reasonable and necessary' if they are supported by a listing in a major drug compendium, and each of the off-label uses at issue here was supported by a listing in a major drug compendium." Similarly, in the present case, Avastin is approved by the FDA and supported by compendia listings. In his Opposition, Relator expressly states that "this case does not seek to show that the FDA would have acted differently had Genentech told the truth" (Pl.'s Opp'n at 2). Relator cannot make this concession and still argue that prescriptions were Avastin were not "reasonable and necessary."

Third, the Third Circuit has stated that "a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government." U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 309 (3d Cir. 2011). Conditions of payment "are those which, if the government knew they were not being followed, might cause it to actually refuse payment." Id. (citation omitted). Here, Relator has not alleged

that reimbursement to providers of Avastin was conditioned on Genentech's compliance with its reporting requirements. Further, in U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd., No. 10-11043-FDS, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) aff'd, 737 F.3d 116 (1st Cir. 2013), the court found that compliance with reporting requirements is *not* a material precondition to payment. The court in Ge also noted that the procedure that the relator should have taken was to petition the FDA to bring action against the alleged violators. Id. While Relator argues in his Opposition that Ge was incorrectly decided, he does not point to a case that supports this contention.

2) Counts Three and Four

Count three of the Complaint alleges a violation of § 3729(a)(1)(G) of the FCA, which imposes liability on an individual who:

> knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

Count four alleges a violation of § 3729(a)(1)(C), who imposes liability on an individual who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." Relator correctly points out that count three does not require the existence of a false claim and instead involves something known as a "reverse false claim." See United States v. Caremark, Inc., 634 F.3d 808, 815 (5th Cir. 2011). Defendant's Motion to Dismiss does not make any arguments specific to reverse false claims, and this Court will not consider the arguments raised by Defendant for the first time in its Reply Brief. Additionally, this Court will not dismiss count four, as § 3729(a)(1)(C) includes claims for a conspiracy to violate § 3729(a)(1)(G).

B. State Law Claims

Counts five through thirty-two allege violations of state law false claims statutes.

Defendant argues that the state law claims must be dismissed for the same reasons as the federal claims. However, as Defendant points out, "many of [the state statutes] have identical or very similar language to the federal FCA" (Def.'s Mot. at 38). As discussed above, Defendant's Motion does not set forth reasons for dismissing counts three and four of the Complaint, and thus this Court will not dismiss the state law claims by relying on Defendant's arguments for the federal claims. Defendant also argues that the state law claims should be dismissed because they are preempted by the FDCA, relying on Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), to support this proposition. However, Buckman is distinguishable from the present case, as it involved claims based on state tort law rather than claims based on state FCA statutes. See id. at 350 (stating that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA"). Accordingly, this Court will not dismiss Relator's state law claims.

IV. CONCLUSION

For the foregoing reasons, Defendant's Motion to Dismiss is **granted in part and denied in part**. An appropriate order follows this Opinion.

Dennis M. Cavanaugh, U.S.D.J.

Date: January 29, 2014
Original: Clerk's Office
cc: Hon. Joseph A. Dickson U.S.M.J.
All Counsel of Record
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